REMARKS/ARGUMENTS

The Pending Claims

Claims 1 and 7-26 are pending. Pursuant to the restriction requirement, claims 7-14 and claims 21-26 have been withdrawn. Claims 1 and 15-20 currently are subject to examination.

The Amendments to the Claims

Claims 2-6 have been cancelled. New claims 15-25 have been added, which recite substantially the same subject matter formerly recited in claims 2-6, but which recite such subject matter in a different form. Specifically, new claims 15 and 21 specify that the method of claim 1 comprises assaying copy number (claim 15) or expression level (claim 21) of a Cripto-1 gene. Claims 16-20 and 22-26 mirror former claims 2-6, but depend from claims 15 or 21, respectively. The subject matter presented in claims 1 and 15-26 is no different in scope from the subject matter formerly presented in claims 1-6.

No new matter has been added by way of these amendments.

The Restriction Requirement

The Office Action has required restriction of the application to one of the following groups of claims:

Group 1 (claims 1-6), drawn to a method of detecting a neurodegenerative disease in a mammal;

Group 2 (claim 10), drawn to a method of inhibiting progression of a neurodegenerative disease in a mammal using an oligonucleotide that hybridizes to a nucleic acid molecule encoding a *Cripto-1* protein;

Group 3 (claim 11), drawn to a method of inhibiting progression of a neurodegenerative disease in a mammal using an antibody to the *Cripto-1* gene;

Group 4 (claim 12), drawn to a method of inhibiting progression of a neurodegenerative disease in a mammal using a peptide that binds to a *Cripto-1* protein;

Group 5 (claim 13), drawn to a method of inhibiting progression of a neurodegenerative disease in a mammal using a mutant *Cripto-1* protein; and

Group 6 (claim 14), drawn to an isolated oligonucleotide.

The subject matter of former claims 1-6 of Group 1 is now presented in claims 1 and 15-25. Accordingly, Applicants treat Group 1 as encompassing new claims 1 and 15-25.

Upon selection of Group 1 or Group 6, the Office Action requires further restriction of the claims. If Group 1 is elected, Applicants must elect (a) assaying the copy number of a *Cripto-1* gene, or (b) assaying the expression level of a *Cripto-1* gene product. If Group 6 is elected, Applicants must further elect SEQ ID NO: 3 or SEQ ID NO: 4.

The Office Action also indicates that claims 7-9 link the claims of Groups 2-5. Upon allowance of claims 7-9, the restriction requirement as between Groups 2-5 shall be withdrawn, and any claims depending from or requiring all the limitations of claims 7-9 will be rejoined.

Applicants' Election

Applicants elect, with traverse, the claims of Group 1 (former claims 1-6, now claims 1 and 15-25). In conjunction with the Group 1 election, Applicants further elect, with traverse, the method comprising assaying the expression level of *Cripto-1*. Claims 1 and 15-20 read on the elected subject matter.

Discussion of Restriction Requirement

Because the instant application is a national stage application under 35 U.S.C. § 371, the inclusion of more than one invention is permitted if all inventions are so linked as to form a single general inventive concept (MPEP § 1893.03(d)). Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. "Special technical features," as defined by PCT Rule 13.2, refers to those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

The Office Action alleges that the claims of Group 1-6 do not define an invention which makes a contribution over the prior art because the *Cripto-1* gene was known at the time the application was filed. Applicants note that all of the claims, with the exception of claim 14, relate to a method of detecting or inhibiting progression of a neurodegenerative disease in a mammal, which is not disclosed in the prior art. Claim 14 is directed to nucleic acid sequences useful in such a method. Thus, all of the pending claims share at least one special technical feature that makes a contribution over the prior art, and are linked so as to form a general inventive concept. Accordingly, the claims should be examined together for this reason alone.

In addition, the Office Action has not satisfied the two criteria for a proper requirement for restriction between patentably distinct inventions. Specifically, the Office Action has not demonstrated that the inventions of Groups 1-6 are independent or distinct *and* that the examination of all the inventions creates a serious burden on the Examiner. (M.P.E.P. § 803 (emphasis added)). These are two separate criteria that must be satisfied to support a proper restriction requirement. If the subject matter of the pending claims is such that there would be no serious burden on the Examiner to search and examine all of the pending claims at the same time, the examiner is to do so, *even if* the pending claims are drawn to independent or distinct inventions.

In the instant case, the Office has not satisfied either criteria. The Office Action allges that the claims of Groups 1-6 are independent or distinct "for the reasons given above," but no such "reasons" are provided anywhere in the Office Action. The Office Action does not indicate, for example, that the claims satisfy any of the criteria set forth on pages 4 and 5 of the Office Action. The Office Action similarly fails to allege why there would be any serious burden on the Office if required to examine all of the claims together.

Accordingly, Applicants respectfully request that the restriction requirement be withdrawn for this additional reason.

With respect to Applicants' election of the Group 1 claims, Applicants also traverse the Office Action's further restriction of the elected method as between assaying for gene copy number or gene product expression level. Claim 1 is generic to a method that employs either type of assay. More specifically, claim 1 is generic to the subject matter recited in each

of claims 15-25. Thus, claim 1 is a linking claim; however, the Office Action does not recognize claim 1 as a linking claim or treat claim 1 appropriately. Considering the generic nature of claim 1, any proposed restriction as between subject matter encompassed by claim 1 should be made conditional upon the non-allowance of claim 1. If claim 1 is found to be in condition for allowance, Applicants respectfully assert that all of claims 15-25, which depend from and contain all of the elements of claim 1, should be examined together.

Moreover, the Office Action has not set forth sufficient reasoning to support the restriction between the subject matter generically encompassed by claim 1. The Office Action states only that "Methods of assaying copy number have different effects, reagents, and are not obvious variants of methods of assaying gene expression." The fact that the assay methods are not obvious variants of one another does not establish a valid basis for restriction where the subject matter is related (e.g., either assay can be used in the method). Furthermore, the Office Action does not explain what it means by different "effects" or how such a statement supports restriction of the invention. The Office similarly fails to explain why assays that use different "reagents" (which are not recited in the claims) are properly restricted from one another. Thus, the Office Action provides no reasoning to support the notion that all of the subject matter of claim 1 cannot be searched and examined together. In fact, the subject matter of claim 1 (and thus claims 15-25 depending from claim 1) shares a common technical feature that is a contribution over the prior art (e.g., the method recited in claim 1). Furthermore, there would be no additional burden (much less a serious burden) placed on the Office by searching and examining all of the subject matter encompassed by claim 1 together.

For the foregoing reasons, Applicants' request that the additional restriction of the Group 1 subject matter be withdrawn or, at least, made conditional upon the non-allowance of generic claim 1.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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Date: September 24, 2007